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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,091	05/13/2005	Kevin Russel Oliver	T1590YP	2027
210	7590	12/14/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			ULM, JOHN D	
			ART UNIT	PAPER NUMBER

1649

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/535,091	Applicant(s) OLIVER ET AL.	
	Examiner John D. Ulm	Art Unit 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23,29-35 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 29-35 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 23, 29 to 35 and 43 are pending instant application. Claim 23 has been amended and claims 24 to 28, 36 to 42 and 44 to 54 have been canceled as requested by Applicant in the correspondence filed 26 September of 2006.

Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 23, 29 to 35 and 43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements for those reasons of record in the previous office action. As stated therein, the instant claims are drawn to a method for the treatment of circadian rhythm disorders by administering an effective amount of a compound which modulates the activity of a VR2 polypeptide to a patient in need of such treatment. Neither the claimed method nor the required compound are adequately described in the instant specification, which fails to identify even a single actual compound having the required activity and provides neither working examples, sound scientific reasoning or evidence that the administration of a compound that modulates the activity of a VR2 polypeptide has any effect whatever of the circadian rhythm of a mammal.

Applicant has traversed these rejections on the premise that "the present invention lies in the discovery that VR2 modulators can be employed in a method of

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treating sleep-related conditions and disorders” and “not the provision of specific VR2 modulators”. Applicant’s argument that a claim to a method that requires a compound having a specific activity is enabled in the complete absence of a description of the genus of compounds required or even a single example thereof is illogical and legally unsound. To be adequately described and enabled, a process that requires a particular product for its practice clearly requires a written description of that product. Applicant’s attention is directed to M.P.E.P. 2164.01(a) and the decision in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which identifies those factors that are to be considered when determining if undue experimentation is required to practice a claimed invention. It is noted in the instant case that undue experimentation would be clearly required to practice the claimed method because no working examples are provided, no guidance with respect to the identity of the required compound or its route, dosage or duration of administration is provided and the instant specification fails identify an analogous method of the prior art from which this information could be derived. Further, before one could even begin to devise a functioning embodiment of the claimed method, one would first have to engage in the undue experimentation that would be required to make the substantial inventive contribution of discovering the identity of at least one compound that modulates the activity of a VR2 polypeptide as required by the instant claims. As stated in the original rejection, the instant claims are drawn to a process that expressly requires a compound that modulates the activity of a VR2 polypeptide and no such compound is described in the instant specification by using “such descriptive means as words, structures, figures, diagrams, formulas, etc.”.

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Further, there is absolutely no evidence that VR2 modulators can be employed in a method of treating sleep-related conditions and disorders. Applicant is advised that assertions contained in a specification are treated as true if they would be believed to be true by one of ordinary skill in the art **given the evidence of record**. Because there is absolutely no evidence provided by the instant specification or the prior art of record **that the administration of a compound** that “modulates VR2 activity will have any effect whatever on sleep-related conditions and disorders, Applicant’s assertion that VR2 modulators can be employed in a method of treating sleep-related conditions and disorders is not credible to one of ordinary skill in the art of receptor biology in view of the evidence of record, or more precisely, the lack thereof. “Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant’s assertions” (M.P.E.P. 2106.02 II(b)(1)(ii)). Contrary to Applicant’s arguments, one of ordinary skill in the art of molecular biology does not automatically conclude that each and every protein that is expressed in a particular organ or tissue modulates each and every activity associated with that tissue or organ. Therefore, the fact that a VR2 protein “is found to be present in extremely high concentrations” in a part of the brain associated with circadian rhythm disorders does not support a conclusion that the administration of a compound that “modulates” VR2 will have any predictable effect upon one or more of those disorders.

Applicant’s arguments filed 26 September of 2006 have been fully considered but they are not persuasive for those reasons given above.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**JOHN ULM**  
**PRINCIPAL EXAMINER**  
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